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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/487,283	06/07/95	EVANS M	ALX-152.1CIP

HM12/1113

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EXAMINER	
GAMBEL, P	
ART UNIT	**PAPER NUMBER**
1644	29

DATE MAILED: 11/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE
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08/487483

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
644	29

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 6/20/00 ; 9/7/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-23, 25-33 is/are pending in the application.
Of the above, claim(s) 13-17 is/are withdrawn from consideration.
☑ Claim(s) 1-8, 18-23, 28, 31-33, 25, 26 is/are allowed.
☑ Claim(s) 9-12, 27, 29, 30 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 23
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGE--

* U.S. GPO: 1998-441-802, 50209

DETAILED ACTION

1. Claims 1-23 and 25-33 are pending.
Claim 24 has been canceled previously.

Applicant's election with traverse of Group I (claims 18, 18-33, 25-27, 29-31) in Paper No. 25 is acknowledged. The traversal is on the ground(s) that the claims of Groups I-V inclusive can be readily examined in this pre-GATT application since all of these claims relate in one way or another to anti-C5 antibodies .

This is not found persuasive as it relates to Groups III-V (and VI), because Groups III-VI encompass distinct and/or independent inventions for the reasons of record set forth in Paper No. 22, mailed 1215/99. In contrast to applicant's assertions that the Groups relate one way or another to anti-C5 antibodies and that there is no undue burden to search the Groups; the Restriction Requirement enunciated in the Paper No. 22 meets the criterion of distinct and/or independent Inventions.

Upon reconsideration of a previous Restriction Requirement, mailed 4/1/93 (Paper no. 5) and applicant's election without traverse of Groups that would read on instant Groups I and II; Groups I and II, encompassing claims 1-12, 18-23, 25-33 are under consideration in the instant application.

Claims 13-17 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant should amend the first line of the specification to update the status of the priority documents.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. Applicant should avoid the use of novel in the Abstract, as patents are presumed to be novel and unobvious.

5. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 10.

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is reminded that the following and should amend the specification accordingly.
The current address of the ATCC is as follows:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209
See pages 38 and 67 of the specification for example.

Applicant is required to review the specification and make the appropriate corrections.

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).

Upon a review of the instant application (e.g. page 33 of the specification); it is not clear whether the term "KSSKC" is a laboratory designation or refers to a discrete sequence. It is noted that SEQ ID NO:1 is designated as the KSSKC peptide in the Sequence Listing. Applicant is invited to clarify whether the KSSKC is a laboratory designation of SEQ ID NO:1 or represents a discrete sequence, which needs to be in sequence compliance with the sequence rules.

In addition, applicant is required to identify the nucleotide and amino acid sequences in the specification with SEQ. ID NOS., if appropriate.

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. New Matter: Claim 27 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: the "amino acid residues ranges" set forth in claim 27.

Applicant's amendment, filed 5/20/99 (Paper No. 16), does not provide sufficient direction as to the written description of the "amino acid residue ranges" set forth in claim 27.

The specification as filed does not provide sufficient written description for the "amino acid residue ranges" set forth in claim 27.. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations"; as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

10. Written Description: Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification broadly describes and the claims recite as part of the invention the following:

"Nucleic acid molecules encoding C5-specific as well as host cells, vectors and methods of making said C5-specific antibodies.

These nucleic acids encompass a broad range of nucleic acids, encompassing a myriad of anti-C5 antibodies as well as including continuous or discontinuous regions encoding the anti-C5 antibodies as well as a number of modifications such as substitution, insertion or deletion change of nucleotides.

Such nucleic acids do not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification appears to only disclose certain nucleic acid sequences drawn to a particular anti-C5 antibody 5G1.1 antibody and the disclosed appropriate sequences of this particular 5G1.1 antibody meet the written description provision of 35 USC 112, first paragraph.

The specification as filed does not provide written description support for any anti-C5 antibody. With the exception of the particular 5G1.1. antibody-related nucleic acids; the skilled artisan cannot envision all the contemplated nucleotide sequences by the detailed chemical structure of the claimed nucleic acids and associated vectors and host cells; and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only isolated nucleic acids associated with the disclosed 5G1.1 antibody disclosed in the specification as filed but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

11. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acids encoding the disclosed G51.1 antibody (e.g. SEQ ID NOS: 8 and 12), does not reasonably provide enablement for any "nucleic acid" encoding any "anti-C5" antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has not provided sufficient biochemical information (e.g. nucleic acid or amino acid sequence) that distinctly identifies such "nucleic acids" encoding "anti-C5 antibody" other than those encompassed by the specific sequences associated with the disclosed G51.1 antibody. While" nucleic acid encoding anti-C5 antibody" may have some notion of the properties of the "nucleic acids";, claiming biochemical molecules by such properties fails to provide sufficient guidance and direction as to how the skilled artisan can make and use such "nucleic acids" , commensurate in scope with the claimed invention.

It has been well known to those skilled in the art at the time the invention was made that antibodies were highly polymorphic and that minor structural differences such as amino acid substitutions in antibody-antigen interfaces can result in substantially different biological properties (e.g. binding). For example, in one structural context, a very conservative substitution may abolish binding; in another a non-conservative substitution may have very little effect on binding. Current estimates of the potential number of antibody molecules that can be generated by all the known genetic mechanisms are in excess of 10^{18}.

There is insufficient direction or objective evidence as to how to make and to how to use "any nucleic acid encoding any anti-C5 antibody"; given the number of possibilities associated with the myriad of "nucleic acids" and "anti-C5 antibodies".

"It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, making and using nucleic acids encoding the claimed anti-C5 antibodies, while providing or maintaining the claimed activity would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Applicant should limit the "nucleic acids" vector and host cells to the disclosed nucleic acids encoding the G51.1 antibody to obviate this rejection.

12. Claims 29/30: It is apparent that the 5G1.1 antibody and hybridoma are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Applicant is reminded that the following and should amend the specification accordingly.
The current address of the ATCC is as follows:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

13. Upon consideration of applicant's amended claims and the Supplemental Response and evidence, filed 8/31/00 (Paper No. 27) in conjunction with the Interview, held on 6/27/00; the instant anti-C5 antibodies appear to be free of the prior art. The prior art does not appear to teach the anti-C5 antibodies, which bind the alpha chain of human C5, which inhibit complement, which inhibits human C5 binding to C3 or C4 and does not bind human free C5a of the claimed invention.

Accordingly, claims 1-8, 18-23, 25, 26, 28 and 31-33 are deemed allowable.

It is noted that claims 27 and 29-30 would be allowable, if the rejections under 35 U.S.C. 112, first paragraph, are obviated.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 13, 2000